Comments Concerning Performance Standards for Vibro Vulnificus and Vibrio Parahaemolyticus

By

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To

Food and Drug Administration
(Docket No. 98P-504)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

April 20, 1999

Introduction

As a result of HACCP, the following information should assist in assessing performance standards for the Gulf Oyster Industries. In the oyster industry, the harvesting and consumption of raw oyster has lead to a great deal of controversy within the industry, regulatory agencies and the public. Before the Gulf Oyster Industry can grow and gain public acceptance, they have to develop a rationale health and safety context, QA/QC programs, realistic risks viable industrial costs, and rationale performance standards for product food usage. This will be very dependent on the season and regional natural environment.

Background

The above concerns need to be delineated so that the Gulf Oyster Industry can become a growing industry with public acceptance. Food suppliers outside the gulf need the following areas will be briefly elucidated.

1. The infective dosage (health and safety, QA/QC and rationale performance standards).
2. Incidence of disease (realistic risks).
3. Viable costs and public acceptance (viable insurance of infection).

Infective dose

Table 1 elucidates common pathogens effecting man in raw municipal biosolids.

Table 1: Major Pathogens Presents in Raw Domestic sludge[2].

Pathogen Class	Examples	Disease
Bacteria	*Shigella sp.*	Bacillary dysentery
	Salmonella sp.	Salmonellosis (gastroenteritis)
	Salmonella typhi	Typhoid fever
	Vibrio cholerae	Cholera
	Enteropathogenic *Escherichia coli*	A variety of gastroenteric diseases
	Yersinia sp.	Yersiniosos(gastroenteritis)
	Campylobacter jejuni	Campylobacteriosis (gastroenteritis)
Viruses	Hepatitis A	Infectious Hepatitis
	Norwalk virus	Acute gastroenteritis
	Rotaviruses	Acute gastroenteritis
	Polioviruses	Poliomyelitis
	Coxsackie viruses	"flu-like"symptoms
	Echoviruses	"flu-like"symptoms
Protozoa	*Entamoeba histolytica*	Amebiasis (amoebic dysentery)
	Giardia lamblia	Giardiasis (gastroenteritis)
	Cryptosporidium sp.	Cryptosporidiosis (gastroenteritis)
	Balantidium coli	Balantidium (gastroenteritis)
Helminths	*Ascaris sp.*	Ascarisis (roundworm infection)
	Taenia sp.	Taeniasis (tapeworm infection)
	Necator americanus	Ancyclostomiasis (hookworm infection)
	Trichuris trichuria	Trichuriasis (whipworm infection)

From Table 2, the infective dose for *Vibrio cholerae* is 10^3 microbes per 100 milliliters or 10^3 microbes per gram of oyster meat. This observation was substantiated in the literature[9]. In nature, there are two natural *Vibrio* microbes of concern.

1. *Vibrio vulnificus*
2. *Vibrio parahaemolyticus*

Kaysner et al.(1987)[10] isolated *V.vulnificus* at a frequency rate of 5.9% from 529 samples of water, shellfish and sediments in California, Oregon and Washington. The 50% lethal dose in non-treated mice varied from 7.6 CFU for a clinical isolate, which caused the death of a septicemic patient. The infectious dose for *Vibrio vulnificus* has been documented to be less than $2x10^3$ microbes per gram of oyster meat, which are two orders of magnitude below the current FDA criteria of 10^5 microbes/gram of oyster tissue.[3] Interestingly, the *Vibrio parahaemolyticus* infection has been observed in New York at densities less than 200 cfu /gram of oyster meat which is also well below the FDA criteria. From these data, the infective dose for *Vibrio* ranges from 2,000 to 5.0 for *V.vulnificus,* 200 for *Vibrio parahaemolyticus*[3] and 10^3 for *Vibrio cholerae.* [6,7,13] This indicates that the level of *Vibrio* in oyster should be below 100 microbes per gram of tissue, but for public health safety, the densities should be below detectable limits.

Table 2: Reported Infected Dose Data.(Density in Number of Organism /100ml).

Pathogen / Organism	Infective Dose	Range	Reference
Bacteria:			
Clostridium perfringens	10^6	10^6–10^{10}	3,6
Escherichia coli	10^4	10^4–10^{10}	3,5,6,8
Salmonella (various species)	10^2	10^2–10^{10}	3,4,6,7
Shigella dysenteriae	10-10^2	10–10^9	3,4,6,7,9
Shigella flexneri	10^2	10^2–10^9	3,6
Streptococcus faecalis	10^9	10^9–10^{10}	3,6
Vibrio cholerae	10^3	10^3–10^{11}	3,4,6,7
Viruses:			
Echovirus 12	HID50 919 PFU HID1 17 PFU est'd	17- 919 PFU	3,6
Poliovirus	1 TCID50,<1 PFU	4x107 TCID50 for infants .2-5x10^6 PFU for infants	3,6
Rotavirus	HID50 10 ffu HID 25 1 ffu est'd	.9-9x10^6 ffu	7,10
Parasites:			
Entamoeba coli	1-10 cysts	1-10 cysts	3,6
Cryptosporidium	10 cysts	10-100 cysts	8,11
Giardia lamblia	1 cyst est'd	NR	3,6
Helminthes	1 egg	NR	3,6

The rationale for the pathogen control for municipal biosolids is elucidated by the 503 regulations for disinfected Class A biosolid.

The 503 regulations require very stringent limits as a result of potential municipality liability. The criteria of pathogen inactivation levels were ascertained to two to three orders of magnitude below infective dose. For example, the following were the limits with respective density of pathogens per gram with respective density of pathogens per gram with respect to infectivity.[11]

Table 3: 503 Regulations

Microbes	Criteria	Infectivity
Salmonella sp.	<.75 MPN/gram of total solids	10^2 MPN/100 ml or 10^5 MPN/gram of total solids
Viruses(Polio)	<.25PFU/gram of total solids	10^2 MPN/100 ml or 10^2 PFU/gram of total solids
Helminth Eggs Viable *Ascaris* eggs	<.25 viable egg/gram of total solids	1 viable egg /100 ml or 10^2 viable egg /gram of total solids

From the data, USEPA requires at least 10^2 to 10^3 reductions of pathogen densities below the known infectivity criteria, to ensure the safety for potential infection from biosolids.

Realistic risks

At present, the real risk appears to be uncertain. The State of Louisiana states little to no deaths due to Vibrio vulnificus, yet when one looks to the literature the estimated incidence of *Vibrio* infections is between 4.3 and 5 cases per million persons a year, based on data on *V.vulnificus* occurrence in Annapolis, MD and in Florida. Using these data, one would estimate, the total number of *Vibrio* infections in the U.S to between 1,075 and 1,250 cases a year. Using the Florida data (Hlady et al.1996)[12] which showed that *V.vulnificus* accounted for 20% of all *Vibrio* infections in the state over a 13 year period, one can estimate that roughly 20% of 1,075/1,250 i.e 215 to 250 cases of *V.vulnificus* occur in the U.S a year. The cost of treating these cases of *V.vulnificus* is roughly about $500 million. The number of deaths in the U.S due to *V.vulnificus* can be estimated either from the Florida data which showed that septicemia accounts for 53%, and wound infections, and data reported mortality from *V.vulnificus* septicemia to be 56% for septicemia and 40% for wound infections. Using these data, it can be estimated that *V.vulnificus* could cause as many as 207 deaths in the U.S a year.

As a result of these above estimates, the deaths due to *V.vulnificus* appear to be increasing over time from the FDA reported data and literature. The incidence of disease has increased from 10 to 20 reported deaths per year from *V.vulnificus* with an overall death of 200 per year from 1983 t 1995 with overall deaths at 200 to 300 by 1999.[13,14] In addition, the total *Vibrio* infection in the United States has increased from an estimated approximate 1,000 per year in 1994 up to 1,300 per year by 1999. These levels are probably increasing as a result of the ever growing environmental impact due to cultural growth. [14]

The cultural activity in the United States has assisted in this increasing rate of *Vibrio* infections. The salinity in the Gulf and estuaries in the region have been increasing due to the increased demand by the public for freshwater. In addition, the advent of channelization of the Mississippi River and the Mississippi Gulf Outlet has also increased the salination in the Gulf and estuarine waters of South Louisiana. The increase in salinity has caused the waters in the estuaries and bays to increase in temperature (the specific heat of water goes down with increasing salinity) which should increase in the densities of *Vibrio vulnificus* in the oyster beds in South Louisiana and Texas. In addition, the major contamination in this region has been non-points source urban, rural and agricultural runoff, which in turn increase the nutrient and microbial levels in basins such as the Lake Pontchartrain Basin. As this cultural activity increase, the

densities of *Vibrio* in Gulf oyster are continuing phenomenon and the resulting infections have increased from 30 to 200 for *Vibrio vulnificus* and 300 to over 1,300 for *Vibrio parahaemolyticus* over the last ten years.

The concerns that are illustrated in this proposal are just what the real risk of obtaining *Vibrio* infection from *Vibrio vulnificus, Vibrio parahaemolyticus, and Vibrio cholerae.*
The first question is just what is the population at risk and how is it changing with time. With this data, a realistic HACCP program can be developed.

Public Acceptance

The acceptance of consumption of raw oysters has been met with skepticism and a reduction in the demand of oysters. For example, the price per pound of raw oysters dropped 55% from 1990 to 1993 for Gulf and Louisiana oysters when the labeling for health hazards became mandatory, yet the price for Atlantic oysters actually rose from $5.03 to $5.83 per pound or 16% over a six year period as shown in Table 4. The Atlantic oyster is worth almost three times the Gulf oyster. Interestingly, in 1997, the cost of the Atlantic oyster dropped from $2.00 as a result of a *vibro parahaemolytical* outbreak from Long Island oysters. Bartholomew[16] noted that all chef/managers in New York City would not buy or use Gulf oysters for over the past ten years. These managers felt the potential to affect their business as result of illness was not with the risk or liability. This has been a result of uncertainty in possible infections due to *Vibro vulnificus* and *Vibro parahaemolyticus*.

Table 4: Cost in Dollars Per Pound of Oyster.

Year	Pacific	Gulf	Atlantic	Louisiana
1980	0.86	1.27	1.45	1.63
1981	1.00	1.43	1.61	1.78
1982	1.01	1.24	1.71*	1.35
1983	0.95	-	-	1.33
1984	1.23	1.58	2.33*	1.81
1985	1.33	1.62	-	1.66
1986	1.53	1.90	2.46*	1.93
1987	-	2.59	2.94*	2.58
1988	1.68	2.39	3.60*	2.36
1989	1.77	2.81	4.45*	2.84
1990	1.90	3.50	5.03*	3.67
1991	1.91	2.58	4.64*	2.64
1992	1.88	2.34	5.31**	2.25
1993	1.97*	1.52	3.83**	1.66
1994	2.49*	1.70	5.66***	1.78
1995	2.44*	1.88	5.29**	1.87
1996	2.48*	2.07	5.84**	2.06
1997	2.46*	2.31	3.52*	2.25

* More expensive than Gulf or Louisiana oysters.
** Double the cost of the Gulf or Louisiana oysters.
*** Triple the cost of Gulf or Louisiana oysters.

Economics to the Industry

The cost per pound of oyster meat has risen for Pacific and Atlantic oysters while the Gulf oyster have fluctuated since 1984 as shown in Table 4. Over the past eight years, the price of oysters at the dock in the Gulf has dropped from 24 cents to 8 cents per oyster. At the same time, the cost of Atlantic cold water oysters has risen to around 40 to 50 cents per oyster, and the dock price is 5 times that of the Gulf Oyster.[14] This cost fluctuation is directly related to the business concerns of the public health safety of oyster consumption. The death costs of the industry has escalated from a few million dollar to over 2 to 300 million dollars as estimated by FDA (2,000,000 per each death). This is a concern since the income from the industry is in the 30 to 50 million dollar.[13] Therefore, it is apparent that the cost can be dropped as the oysters are properly handled, storaged and treated yielding a raw oyster safe for consumption. This should be developed with a rationale HACCP plan that takes this into account.

If the price of Gulf oysters could rise to the cost of Atlantic oysters, the industry could double or triple its profit. Table 5 lists the pounds of oyster produced per year and one can see that 60 percent oyster production occurs in the Gulf while Louisiana has approximately 60% of the Gulf oyster production and one-third overall oyster harvested in the United States. Be developing a very good QA/QC program on *Vibro* densities in oysters, the industry could move into a boom situation.

Table 5:Pounds per Year.

Year	Pacific	Gulf	Atlantic	Louisiana	%Gulf	%Total
1980	6,370,000	13,200,000	28,600,000	6,900,000	50.4	14.2
1981	8,090,000	17,800,000	26,300,000	9,070,000	51.0	17.4
1982	8,620,000	20,300,000	23,700,000	12,600,000	62.1	23.9
1983	7,420,000	-	-	13,200,000	-	-
1984	8,850,000	21,000,000	18,400,000	14,000,000	66.7	29.0
1985	7,560,000	18,900,000	-	14,300,000	75.7	-
1986	10,160,000	15,900,000	16,500,000	12,600,000	79.2	29.4
1987	15,000,000	15,900,000	11,500,000	12,000,000	75.5	28.4
1988	10,300,000	15,500,000	18,300,000	13,200,000	85.2	29.9
1989	10,800,000	15,800,000	7,800,000	11,600,000	73.4	33.7
1990	9,820,000	12,300,000	9,320,000	8,150,000	66.3	25.9
1991	8.720,000	12,300,000	9,000,000	7,270,000	59.1	24.2
1992	8,360,000	13,900,000	11,000,000	9,180,000	66.0	27.6
1993	7,090,000	18,200,000	10,200,000	10,300,000	56.6	27.5
1994	9,330,000	19,300,000	6,800,000	11,300,000	58.5	31.9
1995	9,550,000	20,600,000	7,720,000	13,800,000	67.0	36.4
1996	8,650,000	22,200,000	6,740,000	12,900,000	58.1	34.3
1997	-	22,200,000	-	13,200,000	59.5	-

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